

DOCKET NUMBER: DIA-1003
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE ROOM 1061
ROCKVILLE, MD 20857-0003

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PO. BOX 3
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9516 '99 JUL 28 P1:36

RE: DOCKET NO. 98N-1265

To the FDA:

I send this letter as a consumer of health care services to register my concern and disapproval of the Memorandum of Understanding as published by the FDA on January 21, 1999.

In its present form, the MOU, as well as the Compounding Section 503A of the Modernaztion Act, severely restricts the rights of the physicians and patients to obtain healthcare products from the provider of their choice. It also infringes on the rights of compounding pharmacists to serve the publics medical needs. As a healthcare consumer there should be no restrictions to the delivery of compounded medication prescribed for me, regardless of where I live or travel.
The MOU must be amended!!!

The FDA is an agency of the U.S.Government that purports to be the "watchdog" for consumer safety. THIS IS NOT A SAFETY ISSUE!! As a governmental agency, the FDA also has a responsibility to be accountable to the people. Once again, the MOU must be amended!!

Comments:

It is quite clear what this amendment is about and whose agenda it serves. It is an insult on the American Public's intelligence. It is my Constitutional right to choose which pharmacies I use and the right to use compounded drugs if I choose or need to. By severely limiting the practice and interstate distribution of compounded drugs, the FDA is showing its American citizens it is more interested in being a "lap dog" to Corporate Pharmaceutical Companies and their Patent Drugs, instead of a "Watch Dog" for the people. These large corporations are using the FDA to get rid of any competition and restrict consumer choices to quality alternatives. The FDA is going along with trying to restrict and control my rights! C H833
98N-1265 The FDA has no concern for limiting the same distribution practices for non-compounded prescriptions

as it does for compounded prescriptions), special treatment under the law is called for.

I would like to know who is behind this unfair MOU? Who are, the faces, who came up with these ideas, who wrote it, also, what are their affiliations with and who? I am going to demand to my Senators and House of Representative that an investigation be done into the real agenda of this MOU, because it does not accurately represent the original intent of Congress.

Also, the FDA has made this comment period difficult for the public to respond, there is no E-Mail address, Phone # or Fax # for this MOU, you have refused formal standard rejection letters if there are no written comments, signing and mailing a standard letter is voicing our opinion and should be considered valid. The FDA should have every avenue and opportunity open for public comments, not restrict them so you can say the FDA didn't receive enough. This issue also should be looked into!

It is my Constitutional Right to choose custom-compounded drugs such as those using natural ingredients as an alternative to patented synthetics. I am registering my disapproval of the MOU as currently drafted!

THE MOU MUST BE AMENDED!!

S.C. : HONORABLE BILL PASCRELL, JR.
HONORABLE FRANK LAUTENBERG
HONORABLE DINA TITSCHAKOFF

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